

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA *ex rel.*
ELLSWORTH ASSOCIATES, LLP,

Plaintiff-Relator,

v.

CVS HEALTH CORPORATION, *et al.*,

Defendants.

Case No.: 2:19-cv-2553-JMY

**OPPOSITION TO RELATOR'S
MOTION TO STRIKE DEFENDANTS' AFFIRMATIVE DEFENSES**

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TABLE OF CONTENTS

Table of Authorities	ii
Introduction.....	1
Legal Standard	2
Argument	4
I. The Court should deny the motion to strike.	4
A. Relator has not demonstrated any prejudice from defendants' answer.....	4
B. Defendants' affirmative defenses should not be stricken.	5
1. Defendants' first and second defenses—that relator failed to state a claim—are sufficient.....	5
2. Defendants' third defense—waiver—is sufficient.	7
3. Defendants' fourth defense—estoppel—is sufficient.....	8
4. Defendants' fifth defense—laches—is sufficient.....	9
5. Defendants' sixth defense—unclean hands—is sufficient.	10
6. Defendants' seventh defense—preclusion of attorneys' fees—is sufficient.	11
7. Defendants' eighth defense—lack of standing—is sufficient.	12
8. Defendants' ninth defense—that this non-intervened qui tam action violates separation of powers—is sufficient.	13
9. Defendants' tenth defense—preemption—is sufficient.....	15
10. Defendants' twelfth defense—reserving rights—is sufficient.	16
II. The Court should grant leave to amend to cure any deficiencies.....	17
Conclusion	17

TABLE OF AUTHORITIES

Cases

<i>In re Anthanassious,</i> 418 F. App'x 91 (3d Cir. 2011)	7
<i>Ashcroft v. Iqbal,</i> 556 U.S. 662 (2009).....	3
<i>Bell Atlantic Corp. v. Twombly,</i> 550 U.S. 544 (2007).....	3
<i>U.S. ex rel. Bunk v. Gosselin World Wide Moving, N.V.,</i> 741 F.3d 390 (4th Cir. 2013)	13
<i>Charpentier v. Godsil,</i> 937 F.2d 859 (3d Cir. 1991).....	16
<i>Cintron Beverage Grp., LLC v. Depersia,</i> 2008 WL 1776430 (E.D. Pa. Apr. 15, 2008)	6
<i>Cipollone v. Liggett Grp., Inc.,</i> 789 F.2d 181 (3d Cir. 1986).....	<i>passim</i>
<i>Davis v. Fed. Election Comm'n,</i> 554 U.S. 724 (2008).....	13
<i>Eddy v. Virgin Islands Water and Power Auth.,</i> 256 F.3d 204 (3d Cir. 2001).....	17
<i>Free Enterprise Fund v. Public Co. Accounting Oversight Bd.,</i> 561 U.S. 477, 496 (2010).....	14
<i>Great W. Life Assur. Co. v. Levithan,</i> 834 F. Supp. 858 (E.D. Pa. 1993)	2, 3
<i>Handle v. Brennan,</i> 2018 WL 2002798 (D.N.J. Apr. 30, 2018)	16
<i>U.S. ex rel. Kelly v. Boeing Co.,</i> 9 F.3d 743 (9th Cir. 1993)	14
<i>Knit With v. Knitting Fever, Inc.,</i> 2009 WL 973492 (E.D. Pa. Apr. 8, 2009)	2, 6
<i>United States ex rel. Landis v. Tailwind Sports Corp.,</i> 308 F.R.D. 1 (D.D.C. 2015).....	7, 8

<i>Leventhal v. MandMarblestone Grp. LLC,</i> 2020 WL 2745740 (E.D. Pa. May 27, 2020)	2
<i>Lucia v. SEC,</i> 138 S. Ct. 2044 (2018).....	14
<i>Malibu Media, LLC v. Does 1,</i> 2013 WL 1702549 (E.D. Pa. Mar. 6, 2013).....	3
<i>Malibu Media, LLC v. Lee,</i> 2013 WL 2252650 (D.N.J. May 22, 2013).....	4
<i>Medicaid & Medicare Advantage Prod. Ass'n of Puerto Rico, Inc. v. Emanuelli Hernandez,</i> 58 F.4th 5 (1st Cir. 2023).....	15
<i>U.S. ex rel. Monahan v. Robert Wood Johnson Univ. Hosp. at Hamilton,</i> 2009 WL 4576097 (D.N.J. Dec. 1, 2009).....	7, 9
<i>Monongahela Valley Hosp., Inc. v. Sullivan,</i> 945 F.2d 576 (3d Cir. 1991).....	8
<i>Morrison v. Olson,</i> 487 U.S. 654 (1988).....	14
<i>N. Penn. Transfer, Inc. v. Victaulic Co. of Am.,</i> 859 F. Supp. 154 (E.D. Pa. 1994)	2
<i>New Jersey v. RRI Energy Mid-Atl. Power Holdings, LLC,</i> 2010 WL 3958777 (E.D. Pa. Sept. 30, 2010)	2, 3
<i>Riley v. St. Luke's Episcopal Hosp.,</i> 252 F.3d 749 (5th Cir. 2001)	14
<i>Rohrbach v. NVR, Inc.,</i> 545 F. Supp. 3d 237 (E.D. Pa. 2021)	6
<i>Savage v. Temple Univ. of Commonwealth Sys. of Higher Educ.,</i> 2020 WL 5602651 (E.D. Pa. Sept. 18, 2020)	1, 2, 3
<i>Scherer Design Grp., LLC v. Ahead Eng'g LLC,</i> 764 F. App'x 147 (3d Cir. 2019)	11
<i>U.S. ex rel. Spay v. CVS Caremark Corp.,</i> 2013 WL 1755214, at *3 (E.D. Pa. Apr. 24, 2013)	<i>passim</i>
<i>State Nat'l Ins. Co. v. Cnty. of Camden,</i> 824 F.3d 399 (3d Cir. 2016).....	6

<i>U.S. ex rel. Stone v. Rockwell Int'l Corp.,</i> 282 F.3d 787 (10th Cir. 2002)	14
<i>U.S. ex rel. Taxpayers Against Fraud v. Gen. Elec. Co.,</i> 41 F.3d 1032 (6th Cir. 1994)	14
<i>Tyco Fire Prod. LP v. Victaulic Co.,</i> 777 F. Supp. 2d 893 (E.D. Pa. 2011)	3, 8
<i>United States Honeywell Int'l, Inc.,</i> 841 F. Supp. 2d 112 (D.D.C. 2012).....	7
<i>United States v. Asmar,</i> 827 F.2d 907 (3d Cir. 1987).....	8
<i>United States v. Rite Aid Corp.,</i> 2020 WL 230202 (E.D. Cal. Jan. 15, 2020)	9
<i>Ventures Edge Legal PLLC v. GoDaddy.com LLC,</i> 2017 WL 1075059 (D. Ariz. Mar. 22, 2017)	6, 7
<i>Vermont Agency of Natural Resources v. United States ex rel. Stevens,</i> 529 U.S. 765, 773 (2000).....	12, 13, 14
<i>VICI Racing, LLC v. T-Mobile USA, Inc.,</i> 763 F.3d 273 (3d Cir. 2014).....	11
<i>Weed v. Ally Fin. Inc.,</i> 2012 WL 2469544 (E.D. Pa. June 28, 2012)	3, 7, 9
<i>Wilson v. King,</i> 2010 WL 678102 (E.D. Pa. Feb. 24, 2010)	3
Constitutional Provisions	
U.S. Const. art. II, § 1, cl. 1	13, 14
U.S. Const. art. II, § 2, cl. 2	13, 14
U.S. Const. art., § 3	13, 14
Statutes	
31 U.S.C. § 3730(b)(1)	14
31 U.S.C. § 3730(d)	11
31 U.S.C. § 3730(d)(2)	10, 11

31 U.S.C. § 3730(d)(3)	10
42 U.S.C. § 1395w-26(b)(3)	15
42 U.S.C. § 1395w-112(g).....	15

Other Authorities

5C Charles A. Wright et al., <i>Federal Practice and Procedure</i> § 1381 (3d ed.)	4
Constitution of the United States Article II	13
Fed. R. Civ. P. 7(a)	6
Fed. R. Civ. P. 8(b)(1)(A).....	1, 3
Fed. R. Civ. P. 9(b)	5
Fed. R. Civ. P. 12(b)	1
Fed. R. Civ. P. 12(f).....	4
Fed. R. of Civ. P. 12(h)(2)	6
Fed. R. Civ. P. 15.....	17
Fed. R. Civ. P. 15(a)(2).....	16, 17
Fed. R. Civ. 8(c).....	10
H.R. Rep. 108-391	16
H.R. Rep. 108-391 (2003).....	15

INTRODUCTION

On April 7, 2023, defendants answered the allegations in the amended complaint. ECF No. 57. In addition to responding to the 726 paragraphs in the sprawling second amended complaint, consistent with the plain language of the Federal Rules, Defendants also pled twelve affirmative defenses, including failure to state a claim, failure to plead with particularity, waiver, estoppel, laches, unclean hands, preclusion of attorney fees, lack of standing, violation of separation of powers, preemption, public disclosure bar, and a reservation of rights. ECF No. 57 at 79-80.

Notwithstanding the fact that defendants' assertion of affirmative defenses is both a customary and *required* component of their answer, *see Fed. R. Civ. P. 12(b)* ("Every defense to a claim for relief in any pleading *must be asserted* in the responsive pleading if one is required.") (emphasis added), relator has now moved to strike all but one of them as "insufficient." ECF No. 60. The Court can and should deny that motion to strike in its entirety for at least two reasons:

First, it is well established that striking a defense is a "drastic remedy," and that a motion to strike should be granted only where the moving party demonstrates that it will otherwise suffer prejudice. *Savage v. Temple Univ. of Commonwealth Sys. of Higher Educ.*, 2020 WL 5602651, at *1 (E.D. Pa. Sept. 18, 2020). Relator has made no such showing and has not even meaningfully tried. Relator merely asserts that these defenses may require some additional discovery. But relator has not substantiated that assertion at all, and it is hard to take that position seriously given the quantum of discovery relator already seeks in connection with its own allegations and claims and the obvious and necessary factual overlap of these defenses with the same. In any event, it is relator's burden to show prejudice, and it has categorically not done so.

Second, even assuming relator could demonstrate prejudice (which it cannot), defendants' defenses are plainly sufficient. Critically, and as set forth below, a defendant need only "state in short and plain terms its defenses." Fed. R. Civ. P. 8(b)(1)(A). Defendants had no obligation to plead additional factual or legal detail, nor can a motion to strike be granted for lack of the same.

Moreover, motions to strike cannot be used to resolve questions of law or of fact, which is precisely what relator seeks to have the Court do. Relator has not shown that the insufficiency of *any* of these defenses is “clearly apparent,” (*Cipollone v. Liggett Grp., Inc.*, 789 F.2d 181, 188 (3d Cir. 1986)), not least because relator has not identified any binding precedent foreclosing any of them. The Court should deny relator’s attempt at an end-run around defendants’ right to develop their defenses through discovery, which is improper.

LEGAL STANDARD

“[M]otions to strike are generally viewed with disfavor,” and striking a defense “is a drastic remedy to be resorted to only when required for the purposes of justice.” *Savage*, 2020 WL 5602651, at *1 (quoting *Great W. Life Assur. Co. v. Levithan*, 834 F. Supp. 858, 864 (E.D. Pa. 1993); *N. Penn. Transfer, Inc. v. Victaulic Co. of Am.*, 859 F. Supp. 154, 158 (E.D. Pa. 1994)). The Third Circuit has made clear that district courts “should not grant a motion to strike a defense unless the insufficiency of the defense is ‘clearly’ apparent.” *Cipollone*, 789 F.2d at 188. This means that a “motion to strike will not be granted where the sufficiency of a defense depends on disputed issues of fact [or] disputed and substantial questions of law.” *Leventhal v. MandMarblestone Grp. LLC*, 2020 WL 2745740, at *5 (E.D. Pa. May 27, 2020) (citation omitted); *New Jersey v. RRI Energy Mid-Atl. Power Holdings, LLC*, 2010 WL 3958777, at *4 (E.D. Pa. Sept. 30, 2010) (“A motion to strike an affirmative defense is not appropriate when the sufficiency of the defense depends on disputed issues of fact. Moreover, a motion to strike is not the appropriate procedure to determine disputed or unclear questions of law.” (citations omitted)).

With respect to legal issues, a motion to strike “is not the appropriate procedure to determine disputed or unclear questions of law.” *New Jersey*, 2010 WL 3958777, at *4; *see also Leventhal*, 2020 WL 2745749, at *5 (a “motion to strike will not be granted where the sufficiency of a defense depends on ... disputed and substantial questions of law”); *Knit With v. Knitting Fever, Inc.*, 2009 WL 973492, at *6 (E.D. Pa. Apr. 8, 2009) (“Even when facts are not in dispute,

a motion to strike is not the appropriate procedure to determine disputed or unclear questions of law.”).

With respect to factual issues, and because a party need only “state in short and plain terms its defenses,” Fed. R. Civ. P. 8(b)(1)(A), “the Defendants are not required to detail the ‘factual basis’ for their defenses,” *Savage*, 2020 WL 5602651, at *6. Instead, “[p]roviding knowledge that the issue exists, not precisely how the issue is implicated under the facts of a given case, is the purpose of requiring averments of affirmative defenses.” *Savage*, 2020 WL 5602651, at *6. In other words, affirmative defenses need only satisfy a notice pleading standard. *Malibu Media, LLC v. Does 1*, 2013 WL 1702549, at *2-3 (E.D. Pa. Mar. 6, 2013). As a result, an affirmative defense survives a motion to strike if “requisite notice is provided where the affirmative defense in question alerts the adversary to the existence of the issue for trial.” *Tyco Fire Prod. LP v. Victaulic Co.*, 777 F. Supp. 2d 893, 901 (E.D. Pa. 2011). A defense categorically does *not* need to comply with the pleading standards applicable to stating a claim for relief as set forth in the Supreme Court’s precedent in *Bell Atlantic Corp. v. Twombly* (550 U.S. 544 (2007)) and *Ashcroft v. Iqbal* (556 U.S. 662 (2009)). *See, e.g., Savage*, 2020 WL 5602651, at *4 (“Contrary to [Plaintiff’s] assertions, the Defendants are not required to detail the ‘factual basis’ for their defenses.”). Even where a plaintiff complains that a defendant has merely interposed a “boilerplate defense,” courts reject such arguments as a recasting of an inapposite “*Twombly* issue” because “the plausibility standard does not apply.” *Weed v. Ally Fin. Inc.*, 2012 WL 2469544, at *4 (E.D. Pa. June 28, 2012).

In addition, and even assuming a plaintiff can establish the above, the moving party must also demonstrate prejudice before a court will strike a defense. *Great W. Life Assur.*, 834 F. Supp. at 864; *see also New Jersey*, 2010 WL 3958777, at *4 (E.D. Pa. Sept. 30, 2010). That is, “even if a motion to strike is technically appropriate and well-founded, motions to strike defenses as insufficient are often denied in the absence of a showing of prejudice to the moving party.” *New Jersey*, 2010 WL 3958777, at *4 (quoting *Wilson v. King*, 2010 WL 678102, at *4 (E.D. Pa. Feb.

24, 2010)); *see also Malibu Media, LLC v. Lee*, 2013 WL 2252650, at *6 (D.N.J. May 22, 2013) (“even where the challenged material is redundant, immaterial, impertinent, or scandalous, a motion to strike should not be granted unless the presence of the surplusage will prejudice the adverse party.”) (citations omitted); 5C Charles A. Wright et al., *Federal Practice and Procedure* § 1381 (3d ed.) (“Motions to strike a defense as insufficient are not favored by the federal courts because of their somewhat dilatory and often har[]assing character. Thus, even when technically appropriate and well-founded, Rule 12(f) motions often are not granted in the absence of a showing of prejudice to the moving party.”).

ARGUMENT

I. THE COURT SHOULD DENY THE MOTION TO STRIKE.

The Court should deny relator’s motion to strike in full. *First*, relator has not even attempted to show any prejudice that it may suffer from the presence of any of defendants’ defenses. This itself dooms the motion. *Second*, relator has not identified any “clearly apparent” insufficiency as to any of these defenses; on the contrary, relator’s motion illustrates that each of these defenses presents disputed questions of law and/or fact that cannot be resolved on a motion to strike. Relator’s motion must therefore be denied.

A. Relator has not demonstrated any prejudice from defendants’ answer.

First, relator utterly fails to demonstrate prejudice. Its sole attempt—a throwaway assertion that “permitting these defenses to remain in the case would significantly expand the scope of discovery” (Mot. 1)—is supported by no specifics and is facially incredible in light of the quantum of discovery relator seeks and the obvious factual and legal overlap between relator’s claims and the asserted defenses. Defendants have, to date, made no requests for production focused exclusively on any of the pled defenses, nor do defendants anticipate needing to take additional depositions based solely on the inclusion of affirmative defenses. More generally, it stretches credulity to suggest that a case whose operative complaint stretches to nearly 700 pages of detailed

factual allegations and attachments could or should be meaningfully “streamlined” by preventing defendants from preserving and pursuing their validly pled defenses.

The only specific claim of prejudice relator asserts (without substantiation) is that a single challenged affirmative defense—unclean hands—will result in “extensive, invasive, and wholly irrelevant discovery.” Mot. 7. As an initial matter, even if credited, that assertion would have no bearing on any of the other challenged defenses. Moreover, it is not even true as to unclean hands, because these issues substantially overlap with items for which the defendants are entitled to discovery anyway.

Relator therefore has not demonstrated it will suffer any prejudice from allowing these defenses to proceed and reserving resolution of them for summary judgment or trial. For this reason alone, the Court should deny relator’s motion to strike.

B. Defendants’ affirmative defenses should not be stricken.

Even assuming relator had established prejudice (and it has not), relator has not come anywhere close to demonstrating a “clearly apparent” “insufficiency” in any of defendants’ defenses. Indeed, in this respect relator’s motion generally suffers from two equally fatal flaws: first, while relator attempts to challenge the legal sufficiency of certain defenses, relator provides no binding authority from the Supreme Court or Third Circuit precluding any of defendants’ defenses as a legal matter. Absent such binding authority plainly and clearly preventing the defense, legal insufficiency cannot be established at the motion-to-strike stage. Second, with respect to factual sufficiency, while relator repeatedly argues that the defendants did not plead particular facts supporting their affirmative defenses, defendants are not required to do so at this stage, nor is a lack of particular factual pleading a basis to grant a motion to strike.

1. *Defendants’ first and second defenses—that relator failed to state a claim—are sufficient.*

Defendants’ first and second defenses—that relator failed to state a claim and failed to do so with the particularity required by Rule 9(b)—are specifically authorized by the Federal Rules to be included in an answer. Relator has not cited any binding authority to the contrary.

Federal Rule of Civil Procedure 12(h)(2) provides that “[f]ailure to state a claim upon which relief can be granted … may be raised … in any pleading allowed or ordered under Rule 7(a)” — i.e., an answer — or even “at trial,” and “it is well-settled that a party can set forth the defense of failure to state a claim as an affirmative defense in the answer.” *Cintron Beverage Grp., LLC v. Depersia*, 2008 WL 1776430, at *2 (E.D. Pa. Apr. 15, 2008); *Knit With*, 2009 WL 973492, at *7 (same). That remains true even where, as here, a defendant has previously (and unsuccessfully) moved to dismiss the complaint on similar grounds. See, e.g., *Ventures Edge Legal PLLC v. GoDaddy.com LLC*, 2017 WL 1075059, at *3 (D. Ariz. Mar. 22, 2017) (“district courts have long allowed defendants to plead failure to state a claim as an affirmative defense even when a motion to dismiss on the same grounds had been previously denied.”) (collecting cases). Because the Federal Rules specifically direct—and undeniably allow—the raising of these defenses in an answer, there is no basis for striking them.

Relator contends, in reliance on *U.S. ex rel. Spay v. CVS Caremark Corp.*, that the first and second affirmative defenses should be stricken because they seek “reconsideration of a court’s legal finding” in denying a motion to dismiss. 2013 WL 1755214, at *3 (E.D. Pa. Apr. 24, 2013). That reliance is misplaced. As an initial matter, *Spay* is not binding on this Court and thus does not constitute the sort of binding or controlling authority generally required to grant a motion to strike.

More fundamentally, however, *Spay*’s reasoning is unpersuasive because the Federal Rules specifically permit pleading this defense, and because a district court always has the power to reconsider its prior interlocutory orders. See, e.g., *State Nat’l Ins. Co. v. Cnty. of Camden*, 824 F.3d 399, 406 n.14 (3d Cir. 2016); *Rohrbach v. NVR, Inc.*, 545 F. Supp. 3d 237, 240 (E.D. Pa. 2021) (“[S]o long as [a] district court has jurisdiction over the case, it possesses inherent power over interlocutory orders, and can reconsider them when it is consonant with justice to do so.”) (quoting *In re Anthanassious*, 418 F. App’x 91, 95 (3d Cir. 2011)). Indeed, for just those reasons,

as noted above, other courts to consider the same issue have reached the contrary conclusion, *see, e.g.*, *Ventures Edge Legal PLLC*, 2017 WL 1075059, at *3 (“although the Court denied the Motion to Dismiss in its entirely … it is appropriate to allow this defense to be pleaded in the Answer” because “[a] district court is not bound by law of the case doctrine with respect to an interlocutory order, such as a motion to dismiss, over which it has not been divested of jurisdiction”), one that is consistent with the plain language of the Federal Rules. Moreover, permitting the affirmative defenses to proceed makes especially good sense in the context of this case where discovery will enable the defendants to further amass documents and, in particular, judicially noticeable documents in the possession of the federal government which can and will refute relator’s claims.

Because the Federal Rules expressly permit these defenses, they should not be stricken.

2. *Defendants’ third defense—waiver—is sufficient.*

As an initial matter, as relator’s own authorities acknowledge, waiver defenses are entirely appropriate in False Claims Act cases. *See, e.g., Spay*, 2013 WL 1755214, at *11 (where defendants “allege[] that the government waived and/or ratified [d]efendants’ alleged misconduct through their own actions or knowledge” the defense of waiver should be allowed to “proceed through discovery”); *see also U.S. ex rel. Monahan v. Robert Wood Johnson Univ. Hosp. at Hamilton*, 2009 WL 4576097, at *7 (D.N.J. Dec. 1, 2009) (where “[i]t is possible that evidence procured through discovery will show that the Department of Justice, under the direction of the Attorney General, waived the Government’s claims,” a waiver defense cannot be stricken).

Instead, relator asserts that “CVS pleads no supporting facts.” Mot. 3. But as noted above, no such “factual detail[]” needs to be pled at this stage. *Weed*, 2012 WL 2469544 at *4. Indeed, courts have squarely rejected relator’s argument based on *United States Honeywell Int’l, Inc.* (841 F. Supp. 2d 112, 114-116 (D.D.C. 2012)) that any facts must be pled and have instead confirmed that waiver defenses in FCA cases may proceed through discovery. *See United States ex rel. Landis v. Tailwind Sports Corp.*, 308 F.R.D. 1, 5 (D.D.C. 2015) (collecting cases and rejecting relator’s

argument based on *Honeywell*); Answer, p. 32, *Landis*, No. 10-cv-976 (D.D.C. July 17, 2014), ECF No. 199.

Because defendants provided relator with the “requisite notice … [to] alert[] [relator] to the existence of the issue [of waiver] for trial,” defendants have satisfied the notice pleading standard and defendants’ third affirmative defense should not be stricken. *See Tyco Fire*, 777 F. Supp. 2d at 901.

3. Defendants’ fourth defense—estoppel—is sufficient.

Relator has likewise failed to demonstrate that defendants’ estoppel defense is clearly insufficient, citing no binding authority barring the defense. Mot. 4-5. On the contrary, the Third Circuit “is one of the majority of circuits which recognize the validity of an estoppel defense against government parties.” *United States v. Asmar*, 827 F.2d 907, 912 (3d Cir. 1987); *Monongahela Valley Hosp., Inc. v. Sullivan*, 945 F.2d 576, 589 (3d Cir. 1991); *see also Spay*, 2013 WL 1755214, at *10 (denying motion to strike estoppel defense; “there is no such outright prohibition on the application of equitable estoppel against the government.”).

As a general matter, an estoppel defense requires “(1) a misrepresentation by another party; (2) which he reasonably relied upon; (3) to his detriment,” and (4) “when a party alleges estoppel against the government,” “affirmative misconduct.” *Monongahela Valley Hosp.*, 945 F.2d at 589. As described in defendants’ brief in support of the motion to dismiss, CMS approves the formularies of Part D plan sponsors, including formularies that include a brand drug but not its generic equivalent. ECF No. 35-1 at 3-8. Because the facts concerning the government’s involvement have not been developed through discovery, “a court should restrain from evaluating the merits of a defense.” *Spay*, 2013 WL 1755214, at *10 (quoting *Cipollone*, 789 F.2d at 188). Thus, whether defendants can meet the requirements for invoking estoppel against the government “is inappropriately considered on a Motion to Strike filed prior to the commencement of discovery.” *Id.* at *10 n.12.

4. Defendants' fifth defense—laches—is sufficient.

Relator next argues that the Court should strike the affirmative defense of laches but again cites no binding authority foreclosing the defense. Mot. 5-6.

Although relator argues that the defense of laches is not available against the Government (Mot. 5), “the law on this issue is not [] clear-cut.” *United States v. Rite Aid Corp.*, 2020 WL 230202, at *4 (E.D. Cal. Jan. 15, 2020) (collecting cases). And “[t]here appears to be persuasive authority holding that, at least in limited circumstances [], laches may be applied successfully against the Government” in an FCA action. *Monahan*, 2009 WL 4576097, at *7 (D.N.J. Dec. 1, 2009 (denying motion to strike laches defense in an FCA case)). Relator does not cite any binding Third Circuit precedent barring a laches defense in the context of an FCA action; as a result, the Court should not strike the defense or resolve this “unclear” question of law at this early stage.

Moreover, while relator asserts that this case is only about “monetary damages” (Mot. 5), the second amended complaint expressly seeks *injunctive relief* (SAC, p. 236 ¶ A (asking that defendants “be ordered to cease and desist from submitting or causing to be submitted any more false claims”; p. 236 ¶ G (seeking “an order enjoining CVS Health from continuing to engage in the fraudulent conduct alleged herein”)) and other equitable relief (SAC, p. 236 ¶ D (asking “[t]hat CVS Health be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct”). Relator offers no reason why a laches defense cannot be raised against these requests for equitable relief.¹

And, once again, contrary to relator’s assertion, defendants did not have to include further “factual details” to state a defense based on laches. *Weed*, 2012 WL 2469544, at *4.

Because relator cannot show the insufficiency of this defense to be “clearly apparent,” this

¹ Relator in its motion admits that the False Claims Act does not authorize these forms of equitable relief (Mot. 5), yet relator nonetheless pled requests for such equitable relief and has not withdrawn them. As such, defendants’ affirmative defense of laches should similarly be allowed to proceed.

affirmative defense should not be stricken. *See Cipollone*, 789 F.2d at 188 (internal quotation marks omitted).

5. *Defendants' sixth defense—unclean hands—is sufficient.*

Relator argues that defendants' sixth affirmative defense must be stricken because "courts have repeatedly rejected unclean hands defenses based on a relator's purported misdeeds." Mot. 7. But relator cites no binding precedent, indeed no in-circuit precedent whatsoever, for this proposition. As such, and as explained further above, the unavailability of the defense as a matter of law is not "clearly apparent," and the motion to strike should be denied.²

There are also additional reasons why the unclean hands defense should be permitted to proceed. For starters, where, as here, a relator seeks to recover both attorney's fees and a share of any recovery obtained in the name of the government, the conduct of relator is directly relevant. The FCA specifically provides that a relator may only recover "reasonable expenses" and "reasonable attorneys' fees and costs." 31 U.S.C. § 3730(d)(2). And it further provides that, "if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation." *Id.* § 3730(d)(3).

Relator seemingly admits that its unclean hands is a relevant defense, but asks the Court to effectively make factual determinations at the motion to strike stage. Mot. 6-7, n.5. That, of course, would be improper. Nor does relator's argument that unclean hands is not a defense to *liability* fare any better because defenses are not limited only to those that would bar liability. *Accord Fed. R. Civ. 8(c)* (allowing a party to state any avoidance or affirmative defense); *VICI Racing, LLC v.*

² Defendants do not anticipate asserting unclean hands as to the Government.

T-Mobile USA, Inc., 763 F.3d 273, 299 (3d Cir. 2014) (failure to mitigate is an affirmative defense that “limit[s] [] the plaintiff’s ability to recover damages that could have been avoided”). Relator further argues that a decision about what share relator gets would only be made in a subsequent proceeding involving only relator and the government. Mot. 6-7. But relator specifically seeks relief in the second amended complaint that relator “be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d),” and relator seeks “all attorneys’ fees,” which would run against defendants. SAC, p. 236 ¶¶ C, E. As a result, relator’s unclean hands are appropriately raised as a defense because relator’s pleading puts them at issue by seeking reasonable attorney fees and a share of the proceeds.

Finally, again, as noted above, relator expressly seeks injunctive relief, including injunctions and disgorgement. SAC, p. 235 ¶ A, p. 236 ¶¶ D, G. Leaving aside the question of the substantive basis for such relief (*see supra* n.1), unclean hands would also be a defense to that requested equitable relief. *E.g., Scherer Design Grp., LLC v. Ahead Eng’g LLC*, 764 F. App’x 147, 150 (3d Cir. 2019) (the “unclean hands doctrine … is [] one of the factors the court must consider when deciding whether to exercise its discretion and grant an injunction”) (internal quotation marks omitted).

6. *Defendants’ seventh defense—preclusion of attorneys’ fees—is sufficient.*

Relator next argues that defendants’ seventh affirmative defense—that]relator is precluded from receiving attorney fees—should be stricken because the False Claims Act provides for “reasonable attorneys’ fees and costs.” Mot. 8 (citing 31 U.S.C. § 3730(d)(2)). But relator is only entitled to attorney fees if defendants are found *liable*. 31 U.S.C. § 3730(d)(2) (only authorizing an award where there is a “collect[ion]” from the defendant). What’s more, relator is only entitled to *reasonable* attorneys’ fees that are “necessarily incurred.” 31 U.S.C. § 3730(d)(2). It is thus entirely appropriate to allege a defense that relator is precluded by these applicable provisions from

seeking attorney fees.³

Because relator has not shown that the insufficiency of the seventh affirmative defense is “clearly apparent,” and indeed it is not, defendants’ seventh affirmative defense should not be stricken.

7. *Defendants’ eighth defense—lack of standing—is sufficient.*

Relator contends that the Court should strike the defense that relator lacks standing. Mot. 8-9. But this defense is also sufficient.

In *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, the Supreme Court held that *qui tam* relators have Article III standing to pursue claims in the name of the federal government on the theory that “[t]he FCA can reasonably be regarded as effecting a partial assignment of the Government’s damages claim.” 529 U.S. 765, 773 (2000).

But as defendants have explained in the motion to dismiss briefing, the government did *not* partially assign any of its rights to *this* relator because the public disclosure bar precludes this suit unless the relator is an “original source,” and *this* relator *cannot* be an original source because it is an entity and not an individual. ECF No. 35-1 at 52-54. Thus, the government did *not* partially assign any right to this relator and, as a result, relator lacks Article III standing.

The Court has already concluded that these issues are more appropriately addressed at summary judgment. See ECF No. 49 at 13-17 (“the public disclosure bar and original source exception may involve consideration of matters of fact and, thus, Defendants may reargue these issues at the more appropriate summary judgment phase”). It thus entirely appropriate for defendants to preserve the issue by asserting the defense.

Additionally, a relator lacks Article III standing to pursue only civil penalties in the

³ Furthermore, relator has not limited its request for attorney fees to any particular provision of law. See SAC, p. 236 ¶ E. As such, defendants can appropriately allege that relator is precluded from recovering any attorney fees under whatever provision of law applies to relator’s broadly asserted request for attorney fees.

government's name. Because standing "is not dispensed in gross," a plaintiff "must demonstrate standing for ... each form of relief that is sought." *Davis v. Fed. Election Comm'n*, 554 U.S. 724, 734 (2008) (internal quotation marks omitted). In *Vermont Agency*, the Supreme Court drew a critical distinction between two forms of injury to the United States that are redressed by the FCA: "the injury to its sovereignty arising from violation of its laws (which suffices to support a criminal lawsuit by the Government) and the proprietary injury resulting from the alleged fraud." 529 U.S. at 771. The Court confirmed only that a relator's standing is based on a partial assignment of the government's *damages* claim. *Id.* at 773. The Court did not construe the FCA as assigning the government's claim for injury to its sovereign interests, nor did the Court conclude that such an assignment would be permissible. Rather, by expressly defining the government's assigned interest as the government's "damages" claim, the Court necessarily implied that the assigned interest was the government's "proprietary injury"—i.e., the damages it suffered from the FCA violation.

The Third Circuit has not weighed in on these constitutional questions, and the law and facts are far from clear.⁴ Thus, relator cannot show the insufficiency of this defense at this stage is "clearly apparent" because the law is not settled *and* the facts require further development.

8. *Defendants' ninth defense—that this non-intervened qui tam action violates separation of powers—is sufficient.*

Defendants' ninth affirmative defense alleges that the "[r]elator's prosecution of [this case] violates separation-of-power principles and the Appointments, Executive Vesting, and Take Care Clauses of Article II of the Constitution of the United States." Answer, p. 80. Though relator moves to strike this defense (Mot. 9-12), the Supreme Court has expressly left open "the question whether *qui tam* suits violate Article II, in particular the Appointments Clause of § 2 and the 'take Care' Clause of § 3." *Vermont Agency*, 529 U.S. at 778 n.8. Relator cites no binding precedent from the

⁴ To our knowledge, only one circuit has held that a relator has standing based on a partial assignment of the government's sovereign interests. *U.S. ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, 741 F.3d 390, 403 (4th Cir. 2013).

Third Circuit resolving the question. As a result, a motion to strike this defense is inappropriate.

In particular, the *qui tam* provisions are unconstitutional under the Appointments Clause in either of two ways. Under *Lucia v. SEC* (138 S. Ct. 2044 (2018)) and *Morrison v. Olson* (487 U.S. 654 (1988)), relator is an “[o]fficer[] of the United States” who was not appointed as provided in the Appointments Clause. Alternatively, even if relator is not an officer, then the FCA unconstitutionally vests core Executive functions in nonofficers. The Third Circuit has not weighed in on the question whether the *qui tam* provisions violate the Appointments Clause. In view of the Supreme Court precedent expressly leaving this question open and based on Supreme Court precedent interpreting the Appointments Clause, the unavailability of this defense is not “clearly apparent,” and it should not be stricken.

The *qui tam* provisions also separately violate the Executive Vesting and Take Care clauses because the FCA completely “strip[s]” the President of the power to remove a relator. *See Free Enterprise Fund v. Public Co. Accounting Oversight Bd.*, 561 U.S. 477, 496 (2010). Moreover, the *qui tam* provisions violate the Executive Vesting and Take Care Clauses because they deprive the executive branch of holistic “ability to control” the prosecution of the case. *See Morrison*, 487 U.S. at 685. A relator bringing suit under the *qui tam* provision of the FCA has exclusive authority to initiate a suit, is unconstrained by Justice Department policy, and the Government may not dismiss the action without approval from the court. *See* 31 U.S.C. § 3730(b)(1).

While a number of other circuits have addressed some or all of the above arguments,⁵ the Third Circuit has not weighed in on these important constitutional issues. Because “a motion to

⁵ Only four circuits—all in decades-old decisions—have concluded that the *qui tam* provisions do not violate the Appointments Clause. *U.S. ex rel. Stone v. Rockwell Int'l Corp.*, 282 F.3d 787, 804-805 (10th Cir. 2002); *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 757 (5th Cir. 2001) (en banc, over a dissent); *U.S. ex rel. Taxpayers Against Fraud v. Gen. Elec. Co.*, 41 F.3d 1032, 1041 (6th Cir. 1994) (with a concurrence refusing to join the opinion on the Appointments Clause); *U.S. ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 758-759 (9th Cir. 1993). If these issues were settled, however, there was no reason for the Supreme Court to expressly reserve these questions in *Vermont Agency*.

strike is not the appropriate procedure to determine disputed or unclear questions of law,” *Spay*, 2013 WL 1755214, at *1, and the insufficiency of this defense is not “clearly apparent,” *Cipollone*, 789 F.2d at 188, defendants’ ninth affirmative defense should not be stricken.

9. Defendants’ tenth defense—preemption—is sufficient.

Binding Third Circuit precedent precludes striking defendants’ preemption defense. In *Cipollone*, the Third Circuit observed that “a court should avoid a holding of preemption that is premised on a merely potential conflict between state and federal law” and that “a court should not grant a motion to strike a defense unless the insufficiency of the defense is ‘clearly apparent.’” 789 F.2d at 188. Putting “both of these principles” together, the Third Circuit held that, for a preemption defense, the district court needed to allow “for further development of the claims and theories of the parties … to make informed and definitive rulings on which claims then in contention are preempted.” *Id.*

Here, while defendants do not contend that the False Claims Act is always or even generally preempted, there is no question that issues of preemption are implicated by relator’s claims. The Medicare Part D statute includes an express preemption that provides that “[t]he standards established under this part shall supersede any State law or regulation … with respect to [Part D plans].” 42 U.S.C. § 1395w-112(g) (incorporating 42 U.S.C. § 1395w-26(b)(3) from Medicare Advantage (Part C) into the Part D program). When Congress enacted the text of this express preemption provision in 2003, it observed that the Medicare “program is a federal program operated under rules. State laws, do not, and should not apply, with the exception of state licensing laws or state laws related to plan solvency.” H.R. Rep. 108-391, at 557 (2003) (Conf. Rep.), reprinted in 2003 U.S.C.C.A.N. 1808, 1926; see also *Medicaid & Medicare Advantage Prod. Ass’n of Puerto Rico, Inc. v. Emanuelli Hernandez*, 58 F.4th 5, 12 (1st Cir. 2023) (“Congress intended for all state laws or regulations that purport[] to regulate [Medicare Advantage] plans offered by MAOs … [to be] preempted.” (alterations in original)).

Relator's theory turns on allegations of noncompliance with certain *state* laws. *See SAC ¶¶ 16, 22, 185, 188, 191, 192-201, 203, 206-210.*⁶ Those allegations naturally implicate Congress's clearly stated directive through the express preemption provision above that state laws "do not, and should not apply" to Part D plans. H.R. Rep. 108-391, at 557.

At this juncture, as the Third Circuit clearly directed in *Cipollone*, the Court should "restrain from evaluating the merits of a [preemption] defense where, as here, the factual background for a case is largely undeveloped." 789 F.2d at 188.

10. Defendants' twelfth defense—reserving rights—is sufficient.

Relator cites to no binding precedent for the argument that defendants' twelfth affirmative defense "is not a true defense." Mot. 13. Indeed, the Third Circuit has never held general reservations to be improper or insufficient. What is more, defendants' twelfth affirmative defense is precisely in line with Rule 15(a)(2), which provides that a party may seek leave to amend its pleadings and add an affirmative defense at any time. *See Charpentier v. Godsil*, 937 F.2d 859, 864 (3d Cir. 1991) ("Unless the opposing party will be prejudiced, leave to amend should generally be allowed."); *Handle v. Brennan*, 2018 WL 2002798, at *8 (D.N.J. Apr. 30, 2018) ("The Third Circuit has recognized a party's right to amend its pleading 'at any time by leave of court to include an affirmative defense.'").

Because the Third Circuit has not held a general reservation to be an insufficient affirmative defense, because the defense aligns squarely with Rule 15(a)(2), and because relator cannot show any prejudice on its part if the twelfth affirmative defense remains, it should not be stricken.

⁶ Relator has argued that a federal regulation concerning the meaning of a "valid prescription" incorporates these state laws. While we disagree that the "valid prescription" regulation incorporates state law in the way relator contends and we intend to prove relator wrong through fact development, setting that aside, express preemption of state law is a matter of *Congressional* intent, and federal regulators cannot override the word of Congress. Suffice to say that all these issues necessitate further factual development and cannot be resolved on relator's conclusory motion to strike.

II. THE COURT SHOULD GRANT LEAVE TO AMEND TO CURE ANY DEFICIENCIES.

Should the Court find that any of defendants' defenses are insufficient, defendants seek leave from the Court to amend its answer to re-plead their defenses in accordance with the Court's decision. Under Rule 15, leave to amend an answer "sh[all] [be] freely give[n] ... when justice so requires." Fed. R. Civ. P. 15(a)(2); *see also Eddy v. Virgin Islands Water and Power Auth.*, 256 F.3d 204, 209 (3d Cir. 2001) ("Unless the opposing party will be prejudiced, leave to amend should generally be allowed.").

Therefore, should the Court find that any aspect of defendants' defenses are insufficient, defendants request that the Court grant them leave to file an amended answer to re-plead these defenses.

CONCLUSION

The Court should deny the motion to strike in full.

Dated: June 2, 2023

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CERTIFICATE OF SERVICE

I certify that on June 2, 2023, this document was filed electronically, that it is available for viewing and downloading from the ECF system, and that all counsel of record will be served by the ECF system.

/s/ Edward B. Diskant